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Scientists Say F.D.A. Ignored Radiation Warnings

By GARDINER HARRIS

WASHINGTON — Urgent warnings by government experts about the risks of routinely using powerful CT scans to screen patients for [colon cancer](#) were brushed aside by the [Food and Drug Administration](#), according to agency documents and interviews with agency scientists.

After staying quiet for a year, the scientists say they plan to make their concerns public at a meeting of experts on Tuesday called by the F.D.A. to discuss how to protect patients from unnecessary radiation exposures. The two-day meeting is part of a growing reassessment of the risks of routine radiology. The average lifetime dose of diagnostic radiation has increased sevenfold since 1980, driven in part by the increasing popularity of CT scans. Such scans can deliver the radiation equivalent of 400 chest X-rays.

An estimated 70 million CT (for computed tomography) scans are performed in the United States every year, up from three million in the early 1980s, and as many as 14,000 people may die every year of radiation-induced cancers as a result, researchers estimate.

The use of CT scans to screen healthy patients for [cancer](#) is particularly controversial. In [colon cancer screening](#), for instance, the [American College of Radiology](#) as well as the [American Cancer Society](#) have endorsed CT scans, in a procedure often called a virtual [colonoscopy](#), while the [American College of Gastroenterology](#) recommends direct examinations in which doctors use a camera on a flexible tube.

For patients, navigating the debate can be difficult because doctors, patient advocacy groups and manufacturers often endorse positions that are in their economic self-interest. Radiologists, who often own and use CT machines, for instance, often endorse their use; while gastroenterologists, who often own and use camera scopes, often favor their own methods. Patient groups often get financing from drug and device makers, or physician-specialty groups.

The Food and Drug Administration, charged with sorting out such competing claims, has been just as torn on the issue. The internal dispute has grown so heated that a group of agency scientists who are concerned about the risks of CT scans say they will testify at the Tuesday meeting that F.D.A. managers ignored or suppressed their concerns, and that the resulting delay in making these concerns public may have led hundreds of patients to be endangered needlessly.

Scores of internal agency documents made available to The New York Times show that agency managers sought to approve an application by General Electric to allow the use of CT scans for colon cancer screenings over the repeated objections of agency scientists, who wanted the application rejected. It is still under review.

After an agency official recommended approving G.E.'s application, Dr. Julian Nicholas, a gastroenterologist who trained at [Oxford University](#) and the [Mayo Clinic](#) and worked under contract with the agency, responded by e-mail that he felt strongly that approving the application could "expose a number of Americans to a risk of radiation that is unwarranted and may lead to instances of solid organ abdominal cancer."

Dr. Robert Smith, a former professor of radiology at both [Yale](#) and [Cornell](#) and an F.D.A. medical officer, wrote that he agreed with Dr. Nicholas because "the increased radiation exposure to the population could be substantial and would raise a serious public health/public policy issue," documents show.

Alberto Gutierrez, deputy director of the F.D.A. office with responsibility over radiological devices, said in an interview that the right course on CT colonography was far from clear.

"This device that you've mentioned has not been cleared or approved at this time, and that should tell you that the process we go through is not done," Dr. Gutierrez said.

Arvind Gopalratnam, a spokesman for G.E. Healthcare, wrote in an e-mail message that research had shown that "CT colonography can be a very valuable, noninvasive screening tool to help diagnose colorectal cancer at early stages and ultimately improve overall survival rates."

For decades, scientists at the F.D.A. approved many radiological medical devices with minimal oversight, declaring them modest improvements over older devices and thus not needing extensive reviews or clinical trials to prove their safety and efficacy. But these devices now play a central role in American medicine, helping not only to diagnose a wide array of ailments, but also to treat cancers.

And the agency has done little to assess whether the rapid proliferation of scans is in the best interests of patients, and whether the machines themselves properly protect patients or are beneficial for all of their now-routine uses.

The Times ran a [series of articles](#) this year documenting the harm that can result from mistakes involving medical radiation, leading to a House subcommittee hearing last month and a chorus of calls by radiology groups, researchers, medical physicists and equipment manufacturers for stronger patient protection.

Even [President Obama](#)'s recent physical examination became part of the debate when the president had a virtual, rather than an actual, colonoscopy.

Growing awareness of the risks of scanning led F.D.A. scientists several years ago to begin demanding more and better information from manufacturers to prove that their devices actually were effective for such clinical applications as cancer screening and mapping blood flows in the brain.

But agency managers responded that suddenly changing the rules for the devices would be inappropriate and unfair to manufacturers, documents and interviews show.

The battle between the two sides intensified over a push by some device manufacturers and radiologists to use CT scans routinely to screen healthy patients for lung, colon and other cancers. At stake was another rapid increase in radiation exposures and scans worth hundreds of millions of dollars annually.

General Electric, one of the biggest makers of the devices, told F.D.A. managers that the company wanted CT scans approved for colon cancer screenings because [Medicare](#) officials and private insurers were “actively discussing whether to reimburse for use of CTC for screening asymptomatic individuals” and “to assist their customers in reimbursement for procedures,” internal agency documents show.

Even in the absence of an explicit agency approval, doctors are allowed to use approved medical devices however they see fit. But without an explicit approval, manufacturers are not allowed to market CT machines for colon cancer screening, and insurers often refuse to reimburse the costs of the procedure.

An agency approval of CT colon screening could lead to extensive marketing campaigns, greater acceptance of the procedure by doctors, changes in insurance policies and millions more people having the tests done. Since the agency had approved similar requests for similar uses of CT scans in the past, agency managers said they had little choice but to approve the G.E. application.

The conflict between the two sides escalated throughout 2009, documents show. Minutes of a May 12, 2009, meeting, for instance, reveal that an agency manager, Joshua Nipper, dismissed the scientists’ concerns by saying, “We don’t need to be reinventing a big bugaboo about radiation.” Mr. Nipper did not respond to an e-mailed request for comment.

Dr. Nicholas refused to budge.

“I was first ignored, then pressured to change my scientific opinion, and when I refused to do that, I was intimidated and ultimately terminated,” he said in an interview. “And I’m going to tell the committee exactly that at this meeting.”

As the fight over the G.E. application escalated, Dr. Nicholas, who lives in San Diego, expressed growing concerns in internal e-mails messages that his contract would be allowed to expire — which it did in October.

The day after that expiration, an agency manager, after five months of inaction, began processing the G.E. application by deciding to give G.E. another chance to explain why its application should be approved, documents show.

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